July 8, 1999

1744 '99 JUL 19 P12:03

Dorothy Giebutowski
56 Orchard Lane
Holliston, MA. 01746

To whom it may concern:

It was very upsetting to hear about the restrictive rules governing compounding pharmacies, specifically Docket No. 98N-1265.

For a number of years, I have been purchasing a prescription, especially formulated for my needs from an out of state pharmacy. Prior to that I was taking a synthetic version, and feel that the new medication is a healthier choice, given my circumstances. The fact that I may not be able to purchase this medication at all is downright scary.

Here are my objections to this change:

1. I have confindence in the provider and the medication I am taking. To interfere with the freedom to deal with them is unconscionable. It should not make a difference where I purchase a specially compounded medication, since I am able to purchase standard drugs out of state.
2. The pharmacist...either compounding or otherwise is certainly in a position to advise a doctor about the best route to take pharmacoligically speaking. It always seemed to me that the drug companies have far too much influence on the doctor's decisions on which medication to prescribe. You are going backwards.
3. One size does not fit all. You are unfairly targeting a group that performs a much needed service.

The public is becoming more aware of choices and is increasingly turning to less traditional and healthier treatments.

It is my strong suspicion that the drug companies are in back of this change.

I make it my business to be an informed consumer and research any medications or proposed medications. My nursing background is very helpful. Please reconsider the memorandum.

Yours truly,

Dorothy Giebutowski

Dorothy Giebutowski

98N-1265

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DOCKETS MANAGEMENT BRANCH (HFA-305)
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5630 FISHERS LANE ROOM 1061
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RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernaztion Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the publics medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S.Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Comments:

See attached letter

Signed: Dorothy Gielniewski

State of Residence: Massachusetts

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14 JUL
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